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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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DICKSTEIN SHAPIRO LLP 1825 EYE STREET NW Washington, DC 20006-5403			NAJARIAN, LENA	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/981,752	<b>Applicant(s)</b> SCHMIEDING, REINHOLD
	<b>Examiner</b> LENA NAJARIAN	<b>Art Unit</b> 3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

#### Status

- 1) Responsive to communication(s) filed on 30 April 2008.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-15 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-15 and 17-24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Notice to Applicant***

1. This communication is in response to the amendment filed 4/30/08. Claims 18-24 are newly added. Claims 1-15 and 17-24 are pending.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 19-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19, 20, 21, and 23 recite the limitation "said first act" in line 1 of each of the claims. There is insufficient antecedent basis for this limitation in the claim.

Claim 22 recites the limitation "the provision" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 24 recites the limitation "said second act" in line 1. There is insufficient antecedent basis for this limitation in the claim.

4. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step in independent claims 1, 8, and 14 is: the step of the service provider providing the predetermined specifications and

conditions of a patient to the tissue bank. The dependent claims incorporate the deficiencies of claims 1, 8, and 14 and are also rejected.

***Claim Rejections - 35 USC § 101***

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Under the statute, the claimed invention must fall into one of the four recognized statutory classes of invention, namely, a process (or method); a machine (or system); an article of manufacture; or a composition of matter.

In the present case, claims 1-24 only recite mental steps. In order to qualify as a statutory process, the claim should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state. The recited steps of exemplary claim 1 of merely providing predetermined specifications and conditions of a patient, customizing an allograft at a tissue bank, coordinating delivery of the allograft, and loaning surgical instrumentation are not tied to another statutory class (such as a particular apparatus) and do not transform underlying subject matter (such as an article or materials) to a different state or thing. Therefore, claims 1-24 are deemed to be directed to non-statutory subject matter.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 18, 21, 23, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Bradbury et al. (US 2002/0007294 A1).

(A) Referring to claim 18, Bradbury discloses a method of providing a service, comprising (para. 64 of Bradbury):

receiving at a service provider specifications and conditions of a patient from a medical provider prior to said patient undergoing a predetermined surgical procedure (para. 52, para. 15, and Fig. 2 of Bradbury);

arranging, by said service provider, delivery of an allograft to said medical provider, said allograft being selected based on said specifications and conditions of said patient and also based on said predetermined surgical procedure (para. 15 and para. 13 of Bradbury); and

arranging, by said service provider, delivery of surgical instrumentation to said medical provider for performing said predetermined surgical procedure (para. 28 of Bradbury).

(B) Referring to claim 21, Bradbury discloses wherein said first act of arranging comprises customizing said allograft based on said specifications and conditions of said patient (para. 8 of Bradbury).

(C) Referring to claim 23, Bradbury discloses wherein said first act of arranging further comprises said service provider delivering said allograft to said medical provider (para. 15 of Bradbury).

(D) Referring to claim 24, Bradbury discloses wherein said second act of arranging further comprises said service provider delivering said surgical instrumentation to said medical provider (para. 28 of Bradbury).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-4 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradbury et al. (US 2002/0007294 A1) in view of Filho (6,089,867), and further in

view of Applicant's admitted prior art (admission) given in "Brief Description of the Related Art" section of application.

(A) Claims 1-4 and 8-10 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

11. Claims 5-6 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradbury et al. (US 2002/0007294 A1) in view of Filho (6,089,867), in view of Applicant's admitted prior art (admission) given in "Brief Description of the Related Art" section of application, and further in view of Ramshaw et al. (5,791,907).

(A) Claims 5-6 and 11-12 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

12. Claims 7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradbury et al. (US 2002/0007294 A1) in view of Filho (6,089,867), in view of Applicant's admitted prior art (admission) given in "Brief Description of the Related Art" section of application, and further in view of AORN Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning").

(A) Claims 7 and 13 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

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13. Claims 14, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradbury et al. (US 2002/0007294 A1) in view of Filho (6,089,867), and further in view of Ramshaw et al. (5,791,907).

(A) Claims 14, 15, and 17 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

14. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bradbury et al. (US 2002/0007294 A1) in view of Ramshaw et al. (5,791,907).

(A) Referring to claim 22, Bradbury does not disclose arranging, by said service provider, the provision of technical support to said medical provider for performing said predetermined surgical procedure.

Ramshaw discloses providing technical support to said medical provider for performing said predetermined surgical procedure (col. 1, lines 12-24 and 49-65 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Ramshaw within Bradbury. The motivation for doing so would have been to have a qualified instructor or proctor present to instruct the user (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

15. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradbury et al. (US 2002/0007294 A1) in view of Hoemann et al. (US 2002/0082220 A1).

(A) Referring to claims 19 and 20, Bradbury discloses wherein said first act of arranging comprises arranging, by said service provider, delivery of an implant to said medical provider (para. 15 of Bradbury).

Bradbury does not disclose that the implant is a meniscus allograft and a osteochondral allograft.

Hoemann disclose meniscus and osteochondral allografts (para. 3 and para. 12 of Hoemann).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Hoemann within Bradbury. The motivation for doing so would have been for the service to accommodate various types of allografts.

#### ***Affidavits***

16. The declaration filed on 4/30/08 under 37 CFR 1.131 has been considered but is ineffective to overcome the Bradbury et al. (US 2002/0007294 A1) reference for the following reasons:

(i) MPEP Section 715.02 states the following:

The 37 CFR 1.131 affidavit or declaration must establish possession of either the whole invention claimed or something falling within the claim (such as a species of a claimed genus), in the sense that the claim as a whole reads on it. *In re Tanczyn*, 347 F.2d 830,146 USPQ 298 (CCPA 1965).

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In this case, the averred statements of Reinhold Schmieding and the exhibits attached thereto fail to establish either conception of and/or reduction to practice of the whole invention claimed or something falling within the claim. As such, it is respectfully submitted there is no clear nexus between the materials and the claimed subject matter. In particular, Applicant has not pointed out specific portions of the submitted materials directly tied to the elements or features that are being claimed. The scope of the declaration or affidavit is not commensurate with the scope of the claim(s). For example, the invoice of Exhibit B lacks the steps of providing predetermined specifications and conditions of a patient, customizing the allograft at a tissue bank according to the predetermined specifications and conditions of the patient, coordinating delivery of the customized allograft from the tissue bank to the medical provider, and loaning the surgical instrumentation.

In addition, if the invoice of Exhibit B is meant to show evidence of commercial success, the Examiner respectfully submits that in considering evidence of commercial success objective evidence of nonobviousness including commercial success must be commensurate in scope with the claims *In re Tiffin*, 448 F.2d 791, 171 USPQ 294 (CCPA 1971). Furthermore, care should be taken to determine that the commercial success alleged is directly derived from the invention claimed, in a marketplace where the consumer is free to choose on the basis of objective principles, and that such success is not the result of heavy promotion or advertising, shift in advertising, consumption by purchasers normally tied to applicant or assignee, or other business events extraneous to the merits of the claimed invention, etc. *In re Mageli*, 470 F.2d

1380, 176 USPQ 305 (CCPA 1973). Additionally, the invoice of Exhibit B does not establish a nexus between the claimed invention and the commercial success because there is no evidence that the product or process which has been sold corresponds to the claimed invention, or that whatever commercial success may have occurred is attributable to the product or process defined by the claims *Ex parte Standish*, 10 USPQ2d 1454, 1458 (Bd. Pat. App. & Inter. 1988).

***Response to Arguments***

17. Applicant's arguments filed 4/30/08 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 4/30/08.

(1) Applicant argues that claim 18 is allowable over the cited references since none of the cited references, taken alone or in combination, teaches or suggests to one of ordinary skill in the art that the recited three acts are conducted by the same service provider.

(A) As per the first argument, the Examiner disagrees that the three acts are not conducted by the same service provider. The Examiner respectfully submits that Bradbury teaches a service provider receiving specifications and conditions of a patient (see para. 52, para. 15, and Fig. 2 of Bradbury), arranging delivery of an allograft to a medical provider (see para. 15 and para. 13 of Bradbury), and arranging delivery of surgical instrumentation to said medical provider (see para. 28 of Bradbury).

***Conclusion***

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LENA NAJARIAN whose telephone number is (571) 272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. N./  
Examiner, Art Unit 3626  
In  
7/25/08

/Robert Morgan/  
Primary Examiner, Art Unit 3626